analyses reduce the probability of finding significant results due to chance while large numbers of outcome events reduce the overestimation of treatment effects. Our analysis finds that a statistically significant gain in OS is an important decision driver for even the most critical HTA agencies, although the treatment effect may still be questioned when the trial is unblinded early. HTA agencies appreciate to receive the latest available information (UK, Australia and Germany) and may reject the use of oncology drugs when there is too much uncertainty around OS estimates to justify the proposed price. It is generally useful to continue data collection and follow-up patients should HTA agencies still request more reliable OS estimates for modeling purposes (UK and Australia) or long-term risk-benefit evaluation (France). **CONCLUSIONS:** Payers are aware of the overestimation of effect size due to early trial termination and may reject drugs for high uncertainty around OS estimates. For adequate responses to requests for more reliable data, it is advised to continue data collection and follow-up patients.

PRM221

THE MANAGEMENT OF IRRITABLE BOWEL SYNDROME (IBS) IN ENGLAND: A REAL WORLD STUDY IN PRIMARY CARE CLINICAL PRACTICE

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OBJECTIVES: IBS is often a diagnosis of exclusion, with poor diagnosis coding in primary care and identification of eligible research participants challenging. We present the methodology of an on-going multi-centre, observational, retrospective research study, designed to overcome the challenges of IBS patient identification. **METHODS:** FARSITE, a software tool for identification of research participants developed by the Greater Manchester Comprehensive Local Research Network and North West eHealth, was used to screen anonymised primary care records for potentially eligible patients. Ethical approval reference 13/LO/0692. Search criteria: patients aged 18-60; combination READ code symptoms indicative of IBS and prescription of IBS medications 01/01/2009–31/12/2011. GPs at 8 participating practices in Salford & Greater Manchester reviewed clinical records of the FARSITE-generated list of patients to apply full eligibility criteria for final patient selection. Inclusion criteria: medical diagnosis of IBS or meeting ROME III criteria; provision of consent. Exclusion Criteria: diagnosis excluding IBS; IBS symptoms secondary to other condition; IBS medications only for non-GI symptoms. **RESULTS:** FARSITE identified 1089 (1.3%) patients, of which 297 (27.3%) were eligible. 97 patients consented to participation (79% female). Main reasons for non-eligibility were not meeting ROME III criteria or IBS excluded by medical opinion. Patients were most commonly coded as irritable colon (37%), difficulty defecating (21%), abdominal pain (18%), diarrhoea symptoms (14%). Four (4%) patients had a READ code specific for IBS. The median (IQR) time from 1st presentation with abdominal symptoms to study eligibility was 3.98 (0.00-9.04) years. **CONCLUSIONS:** Identification of patients with IBS using READ codes is sub-optimal in primary care. A combination search of READ codes with symptom and prescription data via FARSITE has enabled potential participants to be identified with a reasonable screening failure rate. FARSITE is a valuable research tool aiding study feasibility by reducing the need for manual patient identification.

PRM222

THE EFFECT OF A LIKELY OVEREMPHASIS ON FICIENCY-RELATED TEST ATTRIBUTES ON ACMG RECOMMENDATIONS AND ACCESS TO NEWBORN SCREENING (NBS)

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OBJECTIVES: Patient access to NBS has been greatly influenced by the 2006 American College of Medical Genetics (ACMG) recommended expansion of NBS. ACMG relied largely on a stakeholder survey on 19 attributes of 84 rare conditions. The percentage of respondents agreeing to an attribute's presence for a condition, along with its weight, determined attribute score. Sums of scores determined the entry point to an algorithm for final recommendations. This research examines 6 attributes that appear to be associated with the same concept and asks whether these are really one (over-weighted) concept. **METHODS:** The ACMG report provided attribute scores. Six questions addressed test efficiency (simplicity, high throughput, cost < $1/condition, multiple analytes/test run, other conditions identified/analyte, multiple conditions detected/test). We examined correlations between the 6 answers for a given condition across conditions and associations with recommendations. **RESULTS:** After eliminating conditions with missing data, 78 remained. Pairwise correlations between the 6 answers were high (mean=.85; range, .72-.96). Of those conditions (37) scoring at least 75% of the possible points on one question ("high throughput"), 79% were recommended as Core conditions to be screened and only 8% were Not Recommended. The mean total scores for the 6 similar questions was 339 (500 possible). Of those (19) scoring 25% or fewer of the possible points for that one question, only 3% were Core, 72% Not Recommended (mean score:89). **CONCLUSIONS:** The high correlations support the idea that the 6 similar questions were answered as if they were the same concept, weighting the common general attribute very highly. A more systematic approach, say MCDA, would likely have eliminated some of these questions with significant consequences for ACMG recommendations.

PRM223

WORKFLOW MAPPING FOR PAEDIATRIC VACCINATION PROCESS IN THE UNITED KINGDOM (UK): A PRECURSOR OF A TIME AND MOTION (T&M) STUDY

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OBJECTIVES: Time and Motion (T&M) methodology allows quantifying time-related outcomes for a health care delivery process by disaggregating the process in its constituent parts to measure task durations. The design of a T&M study requires early process mapping to define the time outcomes to be measured. The mapping of paediatric vaccination process in the United Kingdom (UK), as a precursor of a real-world study, is described. **METHODS:** A targeted review of publicly available information was conducted to gain comprehensive understanding of the paediatric vaccination process in the UK. A survey was designed eliciting the chronology of vaccination process prior to and on vaccination day, including estimates of active health care professional involvement. Face-to-face interviews with a nurse were conducted at three general practitioner surgeries routinely performing vaccinations. A subsequent follow-up call with each nurse was also arranged. Descriptive statistics were generated and preliminary cost calculations made. **RESULTS:** Paediatric vaccination process can be broken down in 6 and 8 clearly discernible steps prior to and on vaccination day, respectively. Activities prior to vaccination day include, among others, inventory, ordering, cold-chain management and are typically for multiple subjects. Mean time for those activities, recalculated per single vaccination visit, was 6.7 minutes, of which 61% dedicated to administrative duties. Activities on vaccination day include, among others, room preparation, consultation, vaccine administration. Estimated time per single visit totaled 25.4 minutes. Estimated total cost per single vaccine administration, with nurse salary cost from PSSRU, was £10.4. Costs may vary substantially depending on the level of "on-costs" to nurse's gross salary. **CONCLUSIONS:** The detailed mapping of paediatric vaccination process in the UK identified clearly discernible tasks, time estimates, factors impacting variability of time outcomes, and early cost estimates. This forms the basis of a real-world T&M study aiming to generate robust time and cost outcomes.

PRM224

COMPARATIVE EFFECTIVENESS RESEARCH OF MEDICAL DEVICES – NEW METHODS NEEDED?

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OBJECTIVES: Guidelines for Health Technology Assessment (HTA) and Comparative Effectiveness Research (CER) largely focus on pharmaceuticals and only few explicitly consider other health care technologies. CER of medical devices (MD) faces some challenges that raise questions about how adequate current CER methods account for the specific features of MD and how well MD fit in the paradigm of drug HTA. Our aim was to identify challenges and gaps in methodology related to specific issues of MD. Our comprehensive framework for the evaluation of clinical effectiveness of MD includes recommendations for generation of primary data and analyzing and synthesizing data in systematic reviews of CER of MD. **METHODS:** We performed a targeted literature review for CER methods and specific features of MD. An electronic database search was combined with systematic screening of tables of content of selected journals in the fields of epidemiology, HTA, statistics, and evidence-based medicine, which have a strong focus on methods. Additionally, we screened the reference lists of the most relevant papers. **RESULTS:** More than 200 publications about the general evaluation of MD and about specific CER methods were included. The MD's physical mechanism of action, the dynamic development and regulatory evidence requirements are the driving features that suggest the increased use of certain methods for the evidence generation, finding of information for HTA, data analysis and synthesis, and interpretation of results. Rather than following the paradigms of drug evaluation, MD resemble more the notion of complex interventions. Our methodological framework is compatible with the EUnetHTA core model and integrates existing recommendations for other complex interventions. The consideration of observational data, operator characteristics, active control trials, and decision-analytic modeling are of special importance, as well as the application of Bayesian methods. **CONCLUSIONS:** The assessment of the clinical effectiveness of MD does require specific, although not necessarily new methods.

PRM225

(COST-) EFFECTIVENESS OF A MULTI-COMPONENT INTERVENTION FOR ADULTS WITH EPILEPSY: STUDY PROTOCOL OF A DUTCH RANDOMIZED CONTROLLED TRIAL

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OBJECTIVES: Poor adherence to anti-epileptic drugs has been shown to be the most important cause of poorly controlled epilepsy. Furthermore, it is emphasized that an increase in quality of life among patients with epilepsy could be reached by counseling and treatments aimed at increasing their self-efficacy and thus stimulate self-management. However, there is a need for evidence on the effectiveness of such programs, especially within epilepsy care. Therefore, we have developed a multi-component intervention (MCI) which combines a self-management/education program with e-Health interventions. Hence the overall objective of this study is to assess the (cost-) effectiveness of a MCI aiming to improve self-efficacy in people with epilepsy compared to care as usual. **METHODS:** A randomized controlled trial in 2 parallel groups will be conducted to compare the MCI intervention with a waiting list control condition in epilepsy patients. One hundred eligible epilepsy patients will be recruited from the Kempenhaeghe epilepsy center and allocated to intervention or control group. Patients in the intervention group will receive an education program of six meetings including e-Health intervention and will be followed for 12 months. Patients in the control group will be followed for 6 months after which they will be offered to participate in the MCI. The study will consist of three parts: 1) a clinical effectiveness study, 2) a cost-effectiveness study, and 3) a process evaluation. The primary outcome will be self-efficacy. Outcome assessments will be done using questionnaires at baseline and after 3, 6, 9, and 12 months. **RESULTS:** N/A. **CONCLUSIONS:** This study will determine the (cost-) effectiveness of an MCI intervention to improve the self-efficacy of epilepsy in adult patients. The MCI is designed to stimulate self-management skills and awareness of epilepsy patients in combination with